

### **REMARKS/ARGUMENTS**

These Remarks are responsive to the Office Action mailed September 8, 2005 ("Office Action"), the Advisory Action ("Advisory Action I") dated January 9, 2006, and the Advisory Action ("Advisory Action II") dated April 10, 2006. Claims 1, 3-5, 8, and 27-29 are pending in the application. Support for the amended claims may be found, e.g., in original claims 7 and 10, and page 5, lines 5-13 of the specification. Specifically, support for the particle size range in the pending claims may be found, for example, at page 5, lines 11-12, of the originally filed specification. Applicant respectfully requests reconsideration of the rejection of the pending claims.

### **STATEMENT OF SUBSTANCE OF INTERVIEW**

Applicant hereby submits a statement of substance of interview under 37 C.F.R. § 1.133. An interview between Examiner Cintins and Applicant's representatives Laurence Posorske and Jeff Vockrodt was conducted at the United States Patent and Trademark Office on February 24, 2006. During the interview, the Mehkeri reference was discussed as well as data from the Bustamante Declaration (see below). Agreement was reached during the interview that Mehkeri does not expressly teach any particular particle sizes for its support material. Applicant agreed to submit data showing that medium size particles have unexpectedly good ability to adsorb *Cryptosporidium* relative to small and large particles. Examiner Cintins stated that support must be found in the specification in order to benefit from the particle size ranges. In response to Examiner Cintins' concern regarding support for the particle size limitations, literal support for the recited ranges can be found, for example, at page 5, lines 11-12, of the originally filed specification. Applicant also submits evidence of unexpected adsorption for particular particle size ranges. See Appendices A-C.

### **Obviousness -- 35 U.S.C. § 103**

The Office Action rejects claims 1, 3-10, and 27 under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,512,491 ("Mehkeri").

The Office Action fails to establish a prima facie case of obviousness of the claimed subject matter. "To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." Manual of Patent Examining Procedure § 2143.03 (8th ed., rev. 2, May 2004). "When evidence of secondary considerations such as unexpected results is initially before the Office, for example in the specification, that evidence should be considered in deciding whether there is a prima facie case of obviousness." M.P.E.P. § 2144.08.

Mehkeri discloses ultra-trace level analysis of water using a coated CELITE (a diatomaceous earth product) support material. Mehkeri, col. 4, ll. 58-67. Coating is accomplished by providing CELITE as a support "upon whose surfaces have been deposited, preferably, a thin layer of freshly-prepared aluminum hydroxide." Mehkeri, col. 3, ll. 7-19. Mehkeri also discloses that "[s]uitable supports include zeolites, kieselghur, fuller's or diatomaceous earth, alumina and silica gel." Mehkeri, col. 3, ll. 9-12. Mehkeri teaches ultra-trace analysis of water for heavy metals, hydrophobic organic substances, insoluble hydroxide of heavy metals, bacterial, protozoa, diatoms, and other microbia including *Cryptosporidium*. Mehkeri, col. 3, ll. 53-67; col. 11, ll. 7-15.

#### **Particle Sizes in the Range of About 0.5 mm to about 1.5 mm**

The claims differ from Mehkeri in that they require, among other limitations, "a surface hydrated alumina ( $\text{Al}_2\text{O}_3$ ) medium having a particle size in the range of about 0.5 mm to about 1.5 mm." As discussed in the interview summary above, Mehkeri is silent as to the particle size of the materials used. However, Mehkeri utilizes CELITE, a diatomaceous earth (DE), which has a biologically determined particle size that is much lower than the particle size required by the claims. See Appendix E, Fig. 3 (less than 0.064 mm) and Appendix F (0.014mm). Specifically, the claims require a particle size range of about 0.5 mm to about 1.5 mm (about 500 to about 1500 microns), which is not met by the much smaller CELITE particles. Thus, the claims differ from Merkeri by requiring a larger particle size than is present in the disclosure of Mehkeri.

Mehkeri teaches using a DE but also states that alumina particles can be used as a support material. As with the CELITE, Mehkeri fails to specify the particle size of the alumina. Accordingly, the Office Action's reliance on alumina does not cure the Mehkeri's deficiency regarding particle size. Moreover, absent any indication to the contrary, a person of ordinary skill in the art would substitute the particles of alumina having a particle size that is on the same order of magnitude as the particle size of CELITE. Thus, to meet the claims one would have to modify Mehkeri by using a particle size for alumina that is more than an order of magnitude larger than the particles of CELITE that Mehkeri actually used. As recognized by the examiner, "one of ordinary skill in the adsorption art would recognize that a given volume of particles having a smaller diameter would produce more surface area, for adsorption of contaminants, than would the same volume of particles having a larger diameter." Advisory Action II, page 2. Indeed, it is well known that for spheres "[t]he specific surface area,  $s$ , is primarily related to the size of the particles and to some extent the shape of the particles. For spheres it is equal to six divided by the diameter." Appendix E, page 48, first full paragraph of column 2. A person of ordinary skill in the art would have had no motivation or reasonable expectation that increasing the particle size of the support material of Mehkeri would lead to any improvement in ultra-trace level analysis of water. The Office Action therefore fails to establish a prima facie case of obviousness under 35 U.S.C. § 103 in view of Mehkeri.

#### **Removal of *Cryptosporidium* with Hydrated Alumina**

Although Mehkeri states that CELITE is moderately directly effective, it does not state that alumina is effective without coating. Moreover, Mehkeri suggests that alumina will perform in a superior manner only if coated with aluminum hydroxide. Mehkeri teaches that CELITE in particular will trap bacteria and protozoa (including *Cryptosporidium*), Mehkeri, col. 11, ll. 8-15, but fails to teach doing so with hydrated alumina as claimed. Finally, Mehkeri treats alumina identically with silica and thus fails to recognize the benefits of using *hydrated* alumina to remove *Cryptosporidium* from water as claimed.

The Office Action recognizes certain differences between the claims and the teachings of Mehkeri, but concludes that it would have been obvious to modify Mehkeri to "dispense with the additional aluminum hydroxide coating suggested by the reference, and to contact the water undergoing treatment directly with the surface of the hydrated alumina, if one were willing to

forgo the advantages associated with this additional coating.” Office Action, page 3. This reasoning fails to set forth a prima facie case of obviousness because the Office Action never gives a reason why a person of ordinary skill in the art at the time of the invention would be “willing to forgo the advantages associated with this additional coating.” “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” M.P.E.P. § 2143.01.I. Furthermore, the teachings of Mehkeri run counter to the claimed invention by stating that a coating of material should be used rather than the uncoated support material. “It is improper to combine references where the references teach away from their combination.” See M.P.E.P. § 2145.X.D (quoting *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)). Finally, merely using the uncoated alumina support in Mehkeri does not meet the limitations of the claims since it is not *hydrated* alumina. The obviousness rationale fails to provide any motivation for practicing the claimed invention and indeed proceeds contrary to the express teachings of Mehkeri. Accordingly, the rejection of claims 1, 3-10, and 27 under 35 U.S.C. § 103 as being obvious over Mehkeri must be withdrawn.

### **Unexpected Results**

“When evidence of secondary considerations such as unexpected results is initially before the Office, for example in the specification, that evidence should be considered in deciding whether there is a prima facie case of obviousness.” M.P.E.P. § 2144.08. “Evidence of unexpected results must be weighed against evidence supporting prima facie obviousness in making a final determination of the obviousness of the claimed invention.” M.P.E.P. § 716.02(c).I (quoting *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978)).

### **Particle Sizes in the Range of About 0.5 mm to about 1.5 mm**

The pending claims require, *inter alia*, removal of protozoa from water by contacting the water with the surface of a surface hydrated alumina, the surface hydrated alumina comprising a particle size of about 0.5 mm to about 1.5 mm. The specification discusses the importance of a similar range (0.5-2 mm) in maximizing collision and capture of biological species by the particles. Specification, page 6, first paragraph.

As discussed above, the examiner recognizes that a person of ordinary skill in the art would want to decrease rather than increase particle sizes in order to increase surface area. However, the Declaration Under 37 C.F.R. § 1.132 of Heriberto Alejandro Bustamante dated February 7, 2006 (“Bustamante Declaration I”) shows that medium size particles (0.5 to 1 mm) unexpectedly provide reasonable removal of oocyst using gravity alone compared to larger particles (2 to 4 mm). Specifically, oocysts were reduced in pilot plant operation by 2.5 to 3.5 logs when using hydrated alumina compared to 0.6 log reduction when using medium sized sand particles. In addition, tests carried out using large particle size hydrated alumina (2 to 4 mm) resulted in less than 10% removal of *Cryptosporidium* oocysts, which is less than a 0.05 log reduction. Appendix B, Bustamante Declaration I, ¶ 23; Appendix C, ¶ 15. This data demonstrates that large particle size hydrated alumina (2 to 4 mm), while suitable for gravity filtration, only removed 10% of the oocysts, while medium size particles of hydrated alumina (0.5 to 1 mm) attained unexpected levels of oocyst removal in the range of 2.5 to 3.5 log reduction while still being capable of gravity filtration. Thus, the medium sized particles of hydrated alumina showed an unexpected ability to adsorb *Cryptosporidium* oocysts.

Furthermore, the Declaration Under 37 C.F.R. § 1.132 of Heriberto Alejandro Bustamante dated September 28, 2006 (“Bustamante Declaration II”) shows that a person of ordinary skill in the art might have estimated that large particle size hydrated alumina would have had sufficient area to adsorb more than 20 million oocysts, but that testing demonstrated that the large particle size alumina was ineffective for oocyst removal in a pilot plant. The specification recognized that 0.5-2 mm particle sizes of hydrated alumina maximize the collision and capture of biological species by the particles. Specification, page 6, first paragraph. Testing has demonstrated this to be true. Thus, even if the person of ordinary skill in the art would have attempted to increase the size of the particles used in Mehkeri (which Applicant contests), he would have thought that large particle sizes have sufficient area to provide significant reductions in *Cryptosporidium* oocysts levels in contaminated water--but he would have been wrong. Applicant has thus demonstrated that the claimed range of particle sizes for hydrated alumina show unexpected results in terms of maximizing the collision and capture of biological species by the particles. Accordingly, evidence of unexpected results demonstrates the nonobviousness of the pending claims under 35 U.S.C. § 103 in view of Mehkeri.

### **Unexpected Removal of *Cryptosporidium* with Hydrated Alumina**

Claims 1, 3-5, 8, and 29 require, *inter alia*, removal of *Cryptosporidium* from water comprising the steps of contacting the water with the surface of a surface hydrated alumina ( $\text{Al}_2\text{O}_3$ ) medium. The largely irreversible adsorption of *Cryptosporidium* on surface hydrated alumina is described throughout the specification. See example II, pages 15-17 and Figs. 7 and 8, which compare retention of *Cryptosporidium* by hydrated alumina relative to silica. Fig. 7 shows that when water containing *Cryptosporidium* is passed through a filter, there is substantial *Cryptosporidium* in the permeate and subsequent rinses when the filter is made up of silica. In contrast, Fig. 8 shows that very little *Cryptosporidium* passes through the filter in the permeate and in subsequent washes when hydrated alumina is used. The Declaration Under 37 C.F.R. § 1.132 of Marilyn Karaman dated March 22, 2002 ("Karaman Declaration") compares the ability of hydrated alumina to retain *Cryptosporidium* relative to a number of other inorganic solids, including silica. See Karaman Declaration, paragraphs 5-6 and Annex B, Fig. 1. In Figure 1, the Karaman Declaration shows that nearly 100% of the oocysts were eluted after a single washing in a silica column, while less than 20% of the oocysts were eluted after seven washings of a hydroxylated alumina column. The evidence in the specification and Karaman Declaration both show that hydrated alumina significantly outperforms silica in trapping *Cryptosporidium*. In contrast, Mehkeri fails to recognize any specific advantages of selecting alumina relative to silica or silica based media such as fuller's earth, diatomaceous earth, and CELITE. Moreover, Mehkeri fails to distinguish between hydrated alumina and alumina that is not hydrated. The obviousness rejection of claims 1, 3-5, 8-10, and 29 is clearly not sustainable in view of the foregoing evidence indicating the unexpected property of hydrated alumina being capable of enhanced adsorption of *Cryptosporidium* oocysts. Accordingly, the rejection of claims 1, 3-5, 8-10, and 29 under 35 U.S.C. § 103 as being obvious over Mehkeri should be withdrawn.

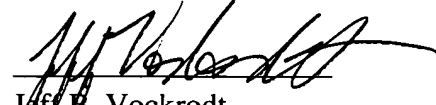
### **Conclusion**

The pending claims are nonobvious in view of Mehkeri under 35 U.S.C. § 103 for all the foregoing reasons. Applicant submits that this response addresses all of the issues raised in the Office Action and places the pending claims in condition for allowance. Should any issues remain to be discussed in this application, the undersigned may be reached by telephone. In the event any variance exists between the amount authorized to be charged to the Deposit Account

and the Patent Office charges for reconsideration of this application, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,  
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